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PRINCIPAL INVESTIGATOR: Jason L. Sperry, MD, MPH

RECIPIENT: University of Pittsburgh  
Pittsburgh, Pennsylvania 15213

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6. AUTHOR(S)  Jason L. Sperry, Barbara Early, Meghan Buck  E-Mail: <a href="mailto:sperryjl@upmc.edu">sperryjl@upmc.edu</a> ; <a href="mailto:earlybj@upmc.edu">earlybj@upmc.edu</a> ; <a href="mailto:buckml@upmc.edu">buckml@upmc.edu</a>				5d. PROJECT NUMBER	
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14. ABSTRACT The enrollment for this study has not yet begun. Pittsburgh site plans to start training of the protocol and research procedures. The remaining sites are in the early phase of submission to their IRB of record for this protocol.  University of Pittsburgh site concluded all community consultation (questionnaires and telephone surveys) on April 2013. Jason Sperry, the PI for this project, was interviewed by local media and explained the purpose of this study to Pittsburgh local and surrounding area.					
15. SUBJECT TERMS Traumatic hemorrhagic shock, thawed plasma, prehospital					
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## Table of Contents

	<u>Page</u>
1. Introduction	1
2. Keywords	1
3. Overall Project Summary	1
4. Key Research Accomplishments	1
5. Conclusion ...	1
6. Publications, Abstracts, and Presentations	&
7. Inventions, Patents and Licenses	&
8. Reportable Outcomes	&
9. Other Achievements	&
10. References	&
11. Appendices	&

**1. INTRODUCTION:**

The primary hypothesis will be to determine the effect of the prehospital infusion (i.e., during air medical transport) of AB plasma (2 units) on 30 day mortality in patients with hemorrhagic shock as compared to standard air medical care. The secondary hypotheses is to determine the effect of the prehospital infusion (i.e., during air medical transport) of AB plasma (2 units) in patients with hemorrhagic shock on clinical outcomes including 24 hour blood transfusion requirements, the development of multiple organ failure, nosocomial infection, acute lung injury (ALI) and transfusion related acute lung injury (TRALI).

**2. KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

**Plasma;** prehospital, hemorrhagic shock

**3. OVERALL PROJECT SUMMARY:** Summarize the progress during appropriate reporting period (single annual or comprehensive final). This section of the report shall be in direct alignment with respect to each task outlined in the approved SOW in a summary of Current Objectives, and a summary of Results, Progress and Accomplishments with Discussion. Key methodology used during the reporting period, including a description of any changes to originally proposed methods, shall be summarized. Data supporting research conclusions, in the form of figures and/or tables, shall be embedded in the text, appended, or referenced to appended manuscripts. Actual or anticipated problems or delays and actions or plans to resolve them shall be included. Additionally, any changes in approach and reasons for these changes shall be reported. **Any change that is substantially different from the original approved SOW (e.g., new or modified tasks, objectives, experiments, etc.) requires review by the Grants Officer's Representative and final approval by USAMRAA Grants Officer through an award modification prior to initiating any changes.**

The IND protocol was submitted to the FDA on May 2012 and it was put on hold on June 14, 2012. The PI and project manager sent response to clinical hold on July 30, 2012. We received FDA authorization to proceed on November 8, 2012.

We received University of Pittsburgh IRB approval for the coordinating center on December 11, 2012.

The protocol was distributed to following participating sites to start preparation to local IRBs and community consultation.

Case Western

Louisville

University of Pittsburgh

University of Tennessee

University of Texas southwestern

Vanderbilt University

University of Pittsburgh IRB approved the protocol for Pittsburgh site on April 8, 2013 for a period of 1 year, with renewal date on March 26, 2014.

The remaining sites are in the process of submitting to their local IRBs starting in July 2013 and the community consultation plan is in the development and implementation stage.

**4. KEY RESEARCH ACCOMPLISHMENTS:** Bulleted list of key research accomplishments emanating from this research. Project milestones, such as simply completing proposed experiments, are not acceptable as key research accomplishments. Key research accomplishments are those that have contributed to the major goals and objectives and that have potential impact on the research field.

**University of Pittsburgh site concluded all community consultation (questionnaires and telephone surveys) on April 2013.**

**Jason Sperry, the PI for this project, was interviewed by local media and explained the purpose of this study to Pittsburgh local and surrounding area.**

**5. CONCLUSION:** Summarize the importance and/or implications with respect to medical and /or military significance of the completed research including distinctive contributions, innovations, or changes in practice or behavior that has come about as a result of the project. A brief description of future plans to accomplish the goals and objectives shall also be included.

**The enrollment for this study has not yet begun. Pittsburgh site plans to start training of the protocol and research procedures. The remaining sites are in the early phase of submission to their IRB of record for this protocol.**

**Our plan is to have all sites approved by their IRB of records at the time of Department of Army final approval to start the enrollment for this study.**

## **6. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:**

- a. List all manuscripts submitted for publication during the period covered by this report resulting from this project. Include those in the categories of lay press, peer-reviewed scientific journals, invited articles, and abstracts. Each entry shall include the author(s), article title, journal name, book title, editors(s), publisher, volume number, page number(s), date, DOI, PMID, and/or ISBN.

- (1) Lay Press:
- (2) Peer-Reviewed Scientific Journals:
- (3) Invited Articles:
- (4) Abstracts:

- b. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (\*) if presentation produced a manuscript.

***Nothing to report***

- 7. INVENTIONS, PATENTS AND LICENSES:** List all inventions made and patents and licenses applied for and/or issued. Each entry shall include the inventor(s), invention title, patent application number, filing date, patent number if issued, patent issued date, national, or international.

***Nothing to report***

- 8. REPORTABLE OUTCOMES:** Provide a list of reportable outcomes that have resulted from this research. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. This list may include development of prototypes, computer programs and/or software (such as databases and animal models, etc.) or similar products that may be commercialized.

***Nothing to report***

- 9. OTHER ACHIEVEMENTS:** This list may include degrees obtained that are supported by this award, development of cell lines, tissue or serum repositories, funding applied for based on work supported by this award, and employment or research opportunities applied for and/or received based on experience/training supported by this award.

***Nothing to report***

For each section, 4 through 9, if there is no reportable outcome, state “Nothing to report.”

- 10. REFERENCES:** List all references pertinent to the report using a standard journal format (i.e., format used in *Science*, *Military Medicine*, etc.).

- 11. APPENDICES:** Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

Attach protocol abstract

## **NOTE:**

**TRAINING OR FELLOWSHIP AWARDS:** For training or fellowship awards, in addition to the elements outlined above, include a brief description of opportunities for training and professional development. Training activities may include, for example, courses or one-on-one work with a mentor. Professional development activities may include workshops, conferences, seminars, and study groups.

***Nothing to report***

**COLLABORATIVE AWARDS:** For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.

**QUAD CHARTS:** If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.

**MARKING OF PROPRIETARY INFORMATION:** Data that was developed partially or exclusively at private expense shall be marked as “Proprietary Data” and Distribution Statement B included on the cover page of the report. Federal government approval is required before including Distribution Statement B. The recipient/PI shall coordinate with the GOR to obtain approval. **REPORTS NOT PROPERLY MARKED FOR LIMITATION WILL BE DISTRIBUTED AS APPROVED FOR PUBLIC RELEASE.** It is the responsibility of the Principal Investigator to advise the GOR when restricted limitation assigned to a document can be downgraded to “Approved for Public Release.” **DO NOT USE THE WORD "CONFIDENTIAL" WHEN MARKING DOCUMENTS.** See term entitled “Intangible Property – Data and Software Requirements” and [https://mrmc.amedd.army.mil/index.cfm?pageid=researcher\\_resources.technical\\_reporting](https://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.technical_reporting) for additional information.